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| 10/019,994 | 11/09/2001 | J. John O'Connor | BUG 2 0147 | 5716 |

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| EXAMINER |
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PREBILIC, PAUL B

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| ART UNIT | PAPER NUMBER |
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3738

DATE MAILED: 09/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,994

Applicant(s)

O'CONNOR ET AL.

Examiner

Paul B. Prebilic

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7 and 9 is/are allowed.
- 6) ☒ Claim(s) 1-6, 8 and 17-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/25/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Objections

Claim 1 is objected to because of the following informalities: On lines 21-22, the language "the natural shapes of said articulating segments" lacks clear antecedent basis. On line 24, the language "the non-fixed axis of rotation" lacks clear antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6, 8, and 17-19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In claims 1-6, 8, and 17-19 which depend upon claim 1, the language "being engaged on a first tibial bone segment" attempts to positively claim a combination of a naturally occurring element (the tibial bone) and a man-made device (the prosthesis); see lines 4-5 of claim 1. For this reason, the claim is directed to non-statutory subject matter. The Examiner suggests changing the words "being engaged" to —adapted to engage— in order to overcome this rejection.

Similarly, on lines 8-9 of claim 1, "being engaged on a second tarsal bone segment" is claiming part of the living organism in combination with the claimed device.

Art Unit: 3738

The Examiner suggests making a corresponding change to this passage as was suggested for lines 4-5 of claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Fournol (US 5,824,106). Fournol anticipates the claim language where the first component as claimed is tibial plate (4) of Fournol, the second component is the astragular plate (2), and the third component is the intermediary element (3); see the figures, the abstract, and column 2, lines 39-67. The third component or intermediary element (3) can slide in both directions on both plates (2) and (4); see column 2, lines 62-67. The non-fixed axis of rotation is permitted by at least the surface between plate (2) and element (3).

Regarding claim 2 specifically, the claim limitations of this claim are dependent upon how the device is mounted, whom the device is implanted into, and how the device is used once implanted. For this reason, the Examiner asserts that the claim language is fully met.

Claims 1-3, 5, 6, 8, 18, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Sammarco (US 5,766,259). Sammarco anticipates the claim language where the first component as claimed is the tibial prosthesis (72) of Sammarco, the

Art Unit: 3738

second component is the talar component (83), and the third component is the floating bearing (96); see Figures 18 and 19, column 7, lines 41-49, and column 8, lines 46-53.

The surfaces are both freely slidable to the extent required by the claims; see the abstract and column 9, lines 36-62. Non-fixed rotation is permitted to some extent because of the loose fit of the floating bearing (96) to the tibial prosthesis (72) and because the bearing (96) is not fixed to the talar component (83). Full congruence is clearly taught; see column 10, lines 4-10.

With regard to claims 5 and 18 specifically, the Examiner asserts that a "partly" anticlastic surface is shown in Figure 19 between the bearing (96) and the talar component (83) because it has both convex and concave surfaces shown. The term "partly" broadens the meaning of this term to encompass this feature shown in Figure 19.

"Partly spherical", however, requires at least part of a spherical surface that slopes away or down from a point on that surface in all directions. For this reason, this language is distinguishable from the structures disclosed by Sammarco and Fournol.

Allowable Subject Matter

Claims 4 and 17 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. "Partly spherical", however, requires at least part of a spherical surface that slopes away or down from a point on that surface in all directions. For this reason, this language is distinguishable from the structures disclosed by Sammarco and Fournol.

Art Unit: 3738

Claims 7 and 9 are allowed over the prior art of record.

Response to Arguments

Applicant's arguments with respect to claims 1-9 and 17-19 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul B. Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic
Primary Examiner
Art Unit 3738